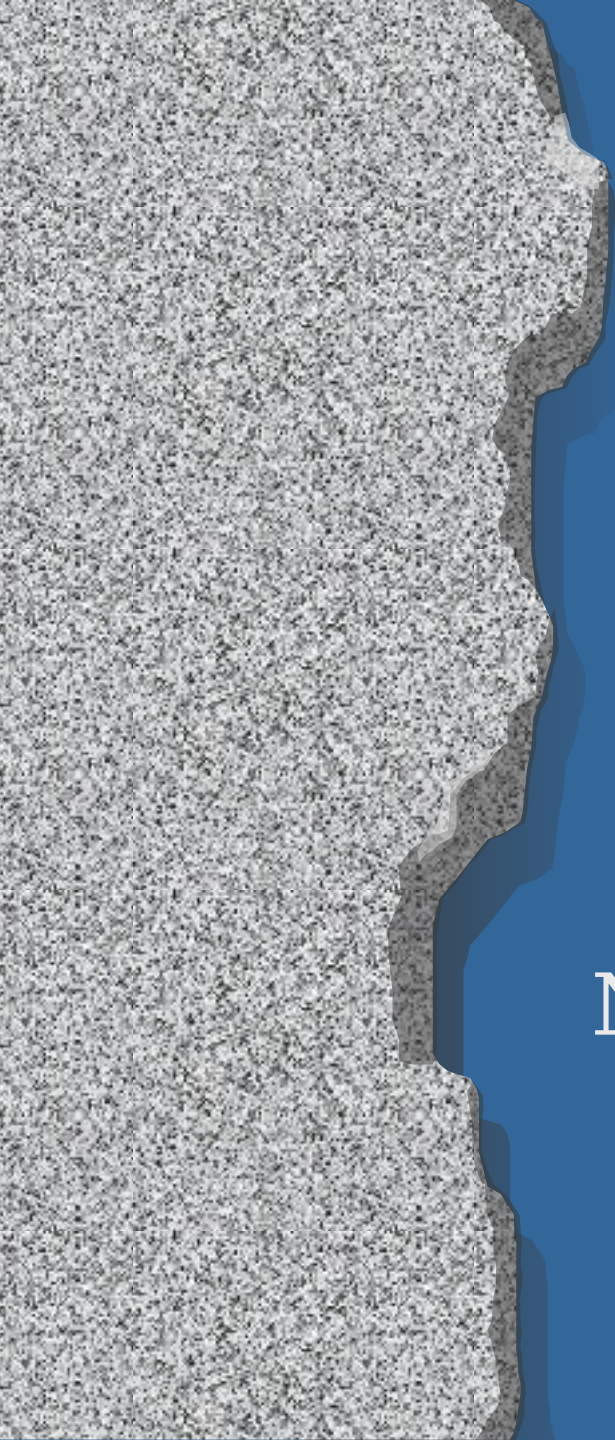




Essentials of Hemodialysis Water Treatment

Kevin C. Abbott, M.D.
Nephrology Service, WRAMC
3 June, 1998

Objectives

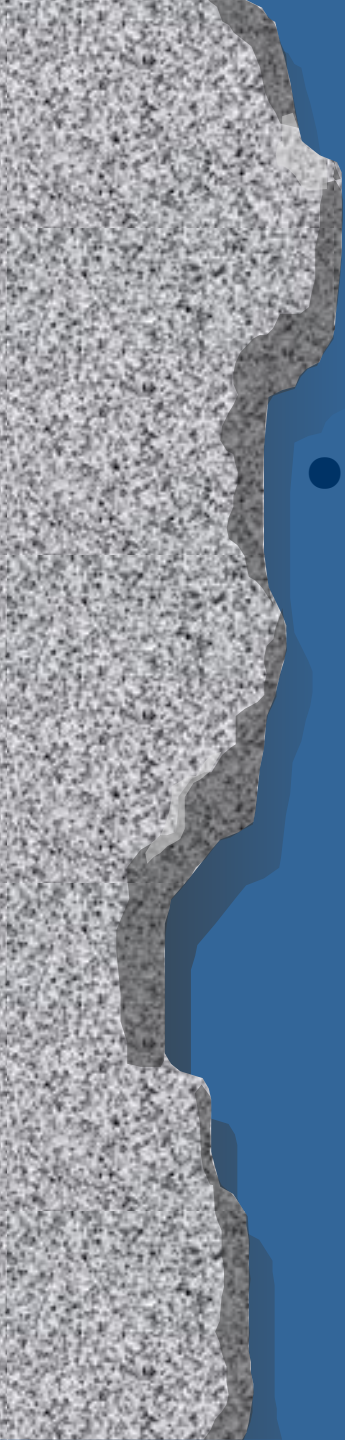
- Identify the steps and components of a typical hemodialysis water treatment system
- Know the monitoring requirements for such systems
- Know the most common pitfalls and dangers in water treatment systems

Water quality

- Critical for hemodialysis
- This topic is rarely if ever formally addressed in nephrology training programs
- Can be disastrous if mishandled (1)

Water standards

- For the community, are based on a water exposure of 2 liters a day (14L/week) and normal renal function (1).
- The hemodialysis patient is exposed to 300L per week. In the past, standard tap water was used for dialysate but many syndromes related to impurities were recognized.



Common contaminants

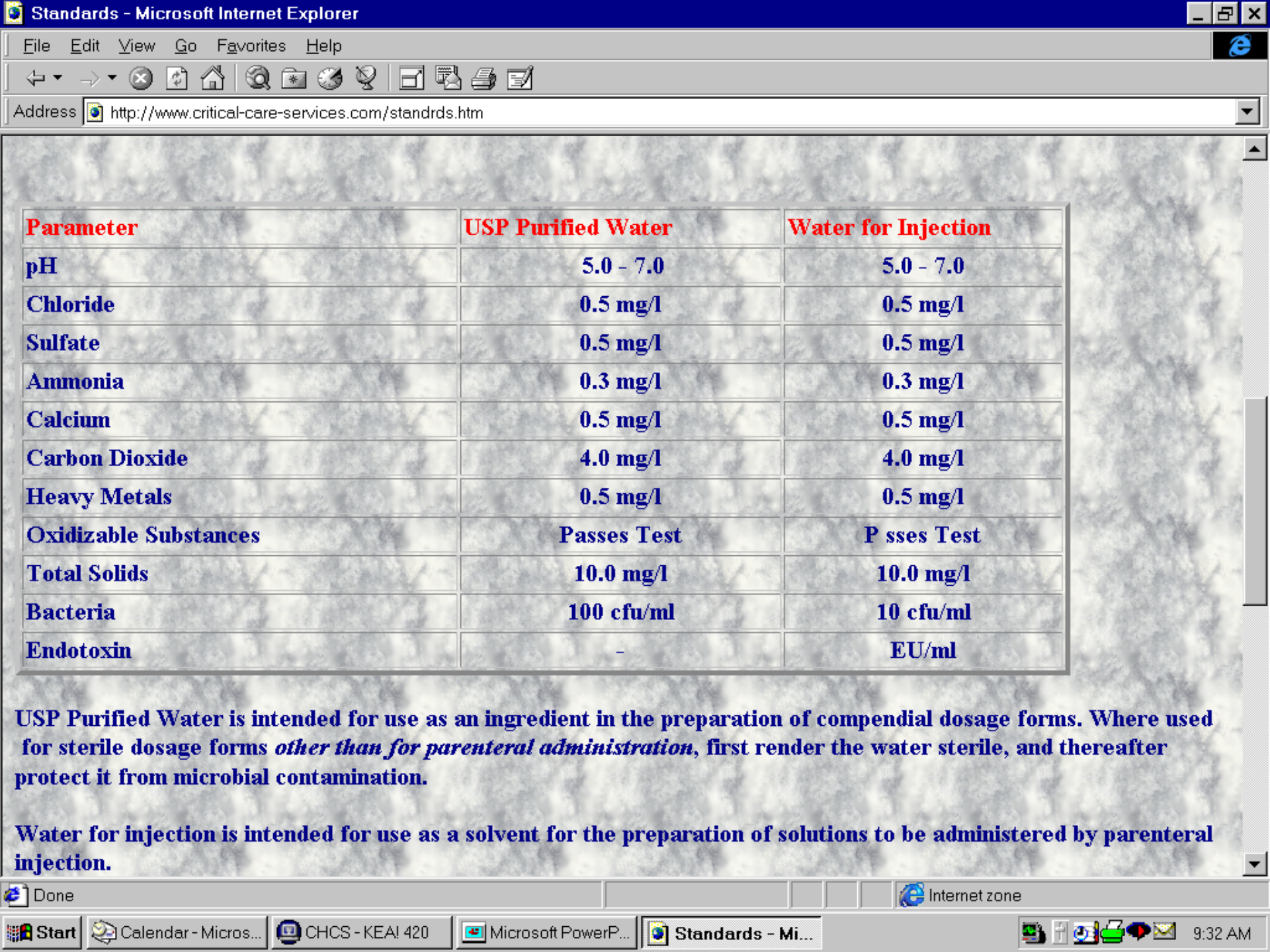
- Aluminum, calcium, magnesium, chloramines, copper, fluoride, nitrate, sodium, sulfate, zinc, microbiologic



On-line Consulting

Hemodialysis Water Standards - ANSI/AAMI RD5-1992 & ANSI/AAMI RD47-1993

Contaminant	Maximum Allowable Level	Contaminant	Maximum Allowable Level
Aluminum	0.010 mg/l	Lead	0.005 mg/l
Arsenic	0.005 mg/l	Magnesium	4.000 mg/l (0.3 mEq/l)
Barium	0.100 mg/l	Mercury	0.0002 mg/l
Cadmium	0.001 mg/l	Nitrate	2.000 mg/l
Calcium	2.000 mg/l (0.1 mEq/l)	Potassium	8.000 mg/l (0.2 mEq/l)
Chloramines	0.100 mg/l	Selenium	0.090 mg/l
Chlorine, Free	0.500 mg/l	Silver	0.005 mg/l
Chromium	0.014 mg/l	Sodium	70.000 mg/l (3 mEq/l)
Copper	0.100 mg/l	Sulfate	100.000 mg/l
Fluoride	0.200 mg/l	Zinc	0.100 mg/l
Total Bacteria Count	200 cfu/ml	Pyrogenicity	5.0 EU/ml



Parameter	USP Purified Water	Water for Injection
pH	5.0 - 7.0	5.0 - 7.0
Chloride	0.5 mg/l	0.5 mg/l
Sulfate	0.5 mg/l	0.5 mg/l
Ammonia	0.3 mg/l	0.3 mg/l
Calcium	0.5 mg/l	0.5 mg/l
Carbon Dioxide	4.0 mg/l	4.0 mg/l
Heavy Metals	0.5 mg/l	0.5 mg/l
Oxidizable Substances	Passes Test	P sses Test
Total Solids	10.0 mg/l	10.0 mg/l
Bacteria	100 cfu/ml	10 cfu/ml
Endotoxin	-	EU/ml

USP Purified Water is intended for use as an ingredient in the preparation of compendial dosage forms. Where used for sterile dosage forms *other than for parenteral administration*, first render the water sterile, and thereafter protect it from microbial contamination.

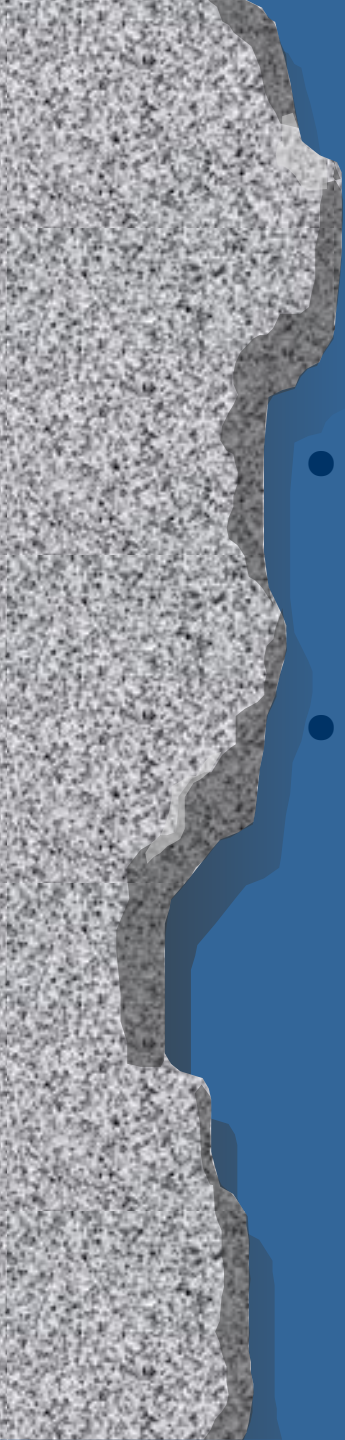
Water for injection is intended for use as a solvent for the preparation of solutions to be administered by parenteral injection.



College of American Pathologists (CAP) Water Standards

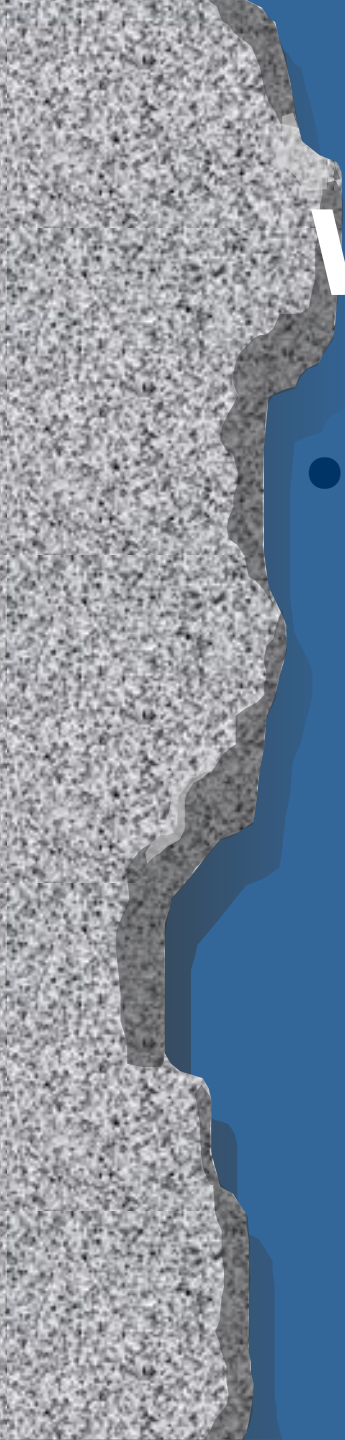
Parameter	CAP I	CAP II	CAP III
Specific Conductance	0.6 microsiemens	1.0 microsiemens	1.0 microsiemens
Specific Resistance	16.6 Megohm/cm	1.0 Megohm/cm	4.0 Megohm/cm
Silica	0.05 mg/l	0.1 mg/l	1.0 mg/l
Heavy Metals	0.01 mg/l	0.01 mg/l	0.01 mg/l
KMNO3 Reduction	60 minutes	60 minutes	60 minutes
Sodium	0.1 mg/l	0.1 mg/l	0.1 mg/l
Hardness	negligible	negligible	negligible
Ammonia	0.1 mg/l	0.1 mg/l	0.1 mg/l
Bacteria	10 cfu/ml	10 cfu/ml	-
pH @ 25 degrees C	-	-	5.0
Carbon Dioxide	3.0 mg/l	3.0 mg/l	3.0 mg/l

[*Return to Homepage*](#)



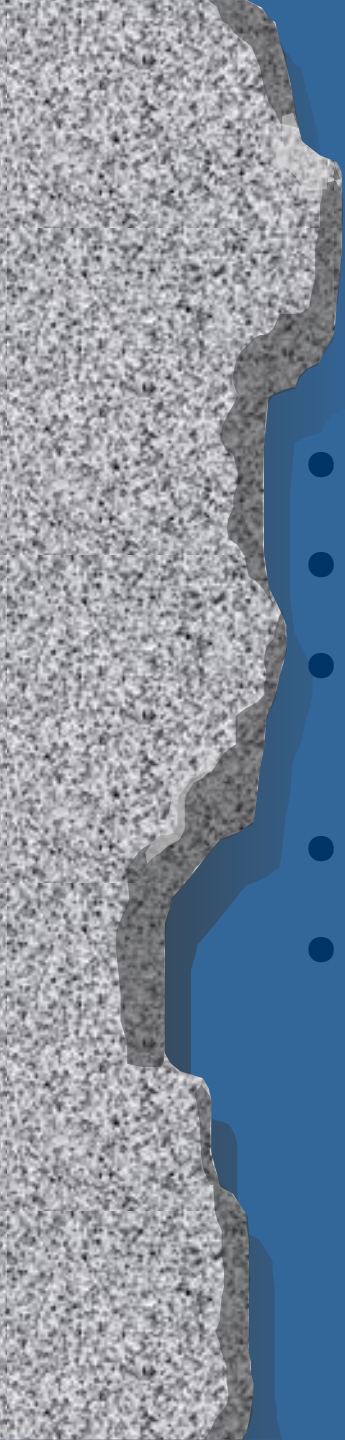
General classes of water treatment

- If hydraulic pressure isn't met at all times, cavitation or degassing can cause an *air-water slurry*. Can destroy an RO pump.
- In contrast to the high flow velocity of the final RO product water (to sustain pressure and, by inducing some turbulence, “scouring” the surfaces to present unstirred layers where bacteria and slime adhere), the pretreatment system uses low flow velocity.



Water treatment design

- Treatment processes and designs can be customized to address the often unique (and changing) patterns of contamination seen in local water supplies

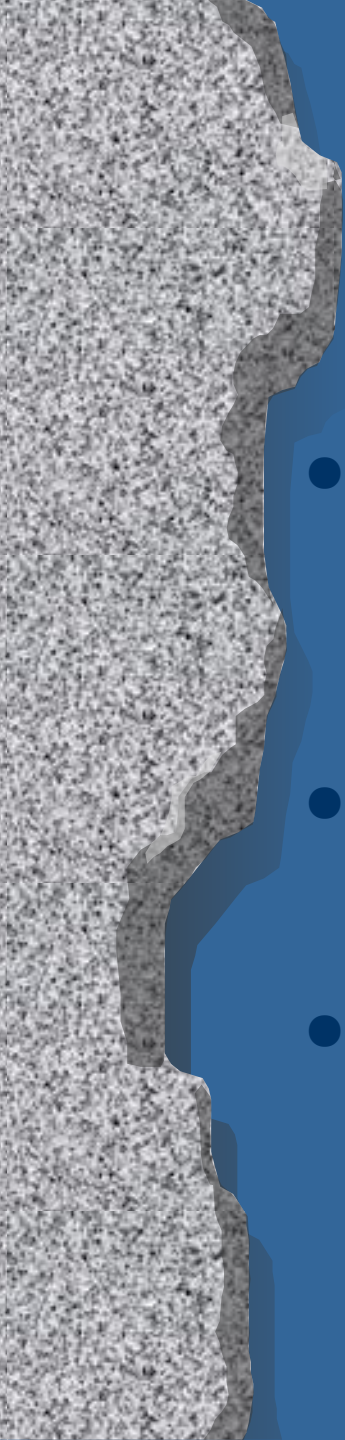


General classes of water treatment

- Particulate filters
- Softeners and deionizers
- Activated carbon filters (sometimes called granulated activated carbon, GAC)
- Ultrafiltration
- Conditioned water has had particulate matter, scaling factors, and volatile inorganic and organic chemicals removed.

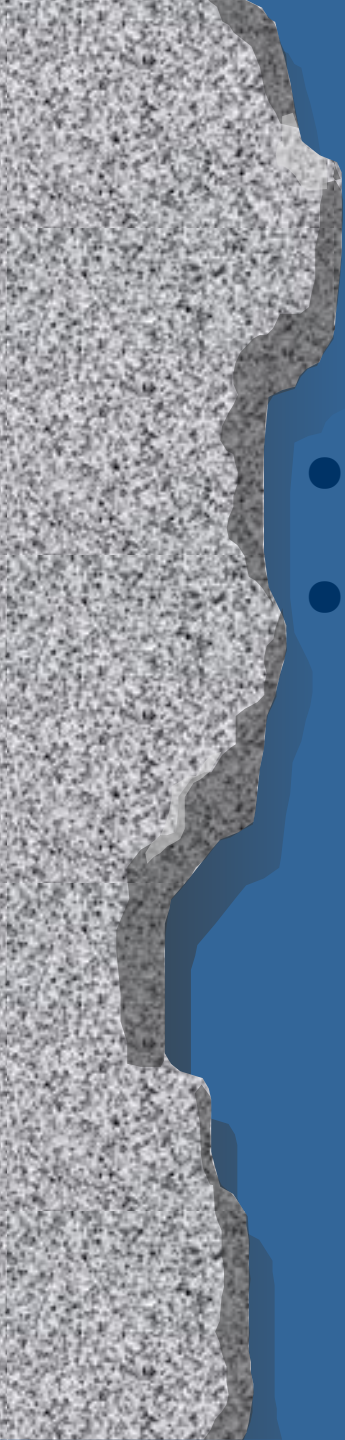
General classes of water treatment

- Cold water (<60 deg F) is difficult to process
- Hot water (>95 deg F) can damage membranes
- Acceptable range is 60-80 deg F (15.5-26.7 deg C), optimal is 77 deg F (25 deg C)



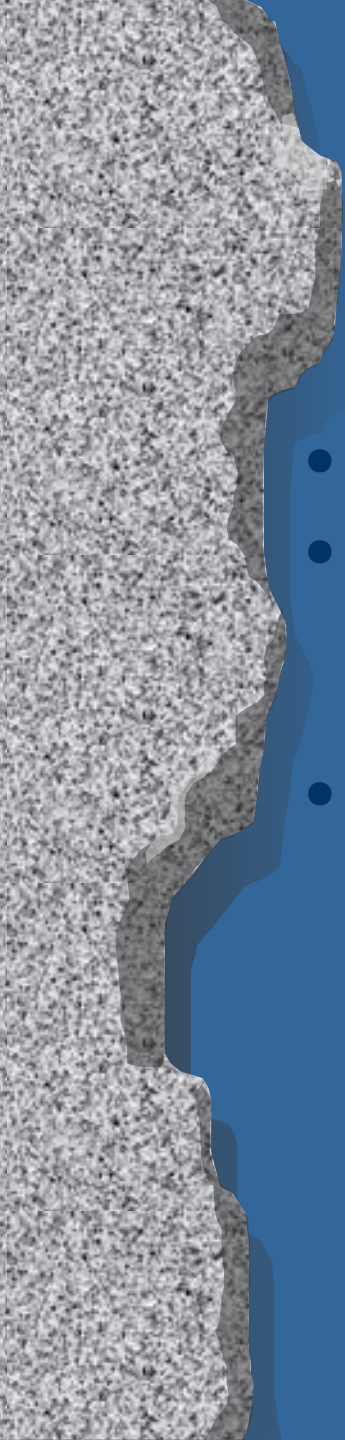
General classes of water treatment

- All water treatment devices depend on adequate hydraulic (not hydrostatic) pressure
- Hydraulic pressure: Pressure of water flowing at a fixed rate
- Hydrostatic pressure: Pressure of stationary water



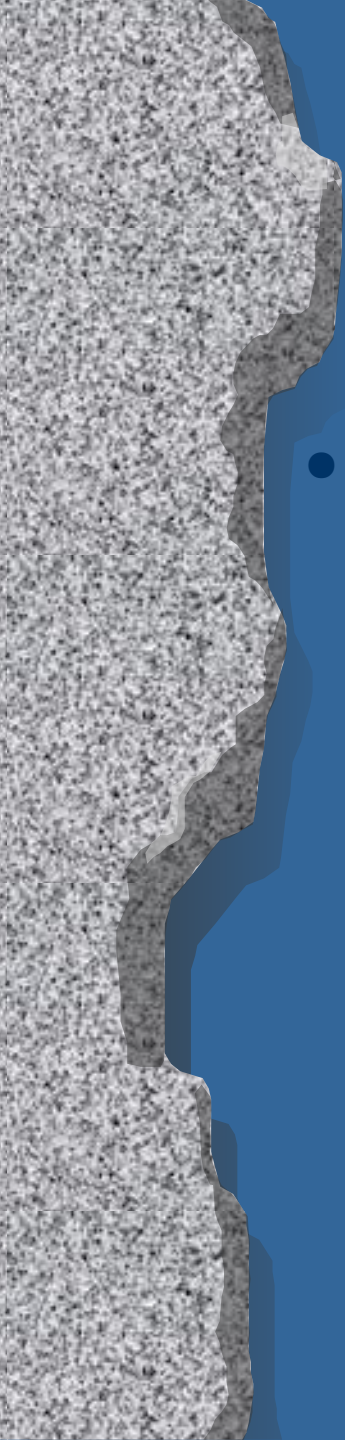
Particulate filters

- Remove large particles
- Some devices can be fouled by these particles, and filters often serve as pretreatment.



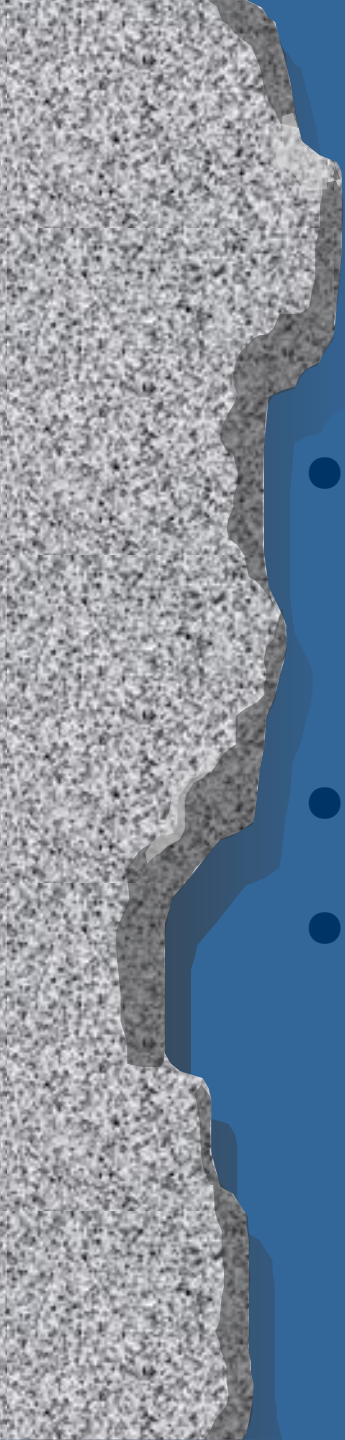
Particulate filters

- First step in primary clarification
- Remove not only visible particles but colloid: substances suspended in water that don't settle when water stops flowing.
- Can include clay, bacteria, and metallic complexes or combinations called *organometallic complexes*. Esp small (<1 micrometer) particles can pass through the 5 micrometer filters before GAC or RO machines



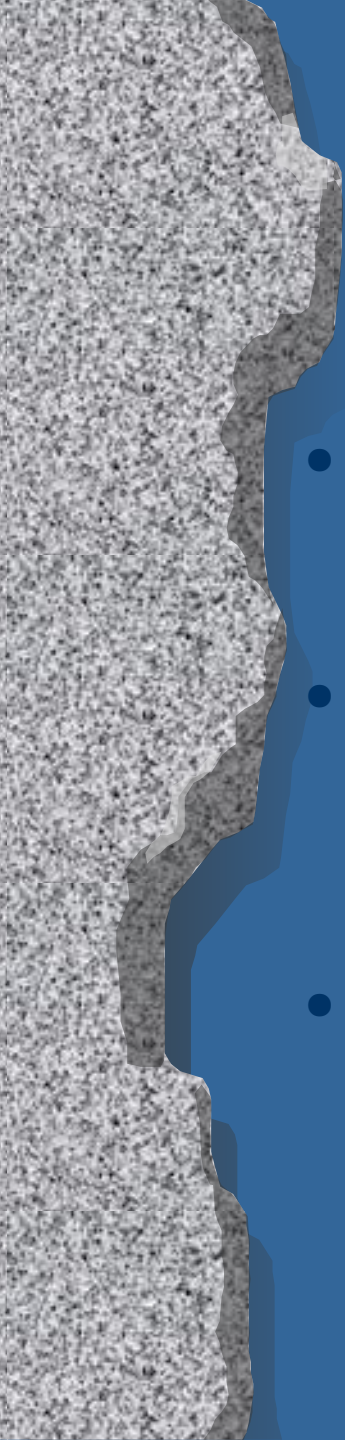
Particulate filters

- Primary clarification better accomplished with multi-media depth filters (MMDF) than single medium. Recommend four layers, from top to bottom:
 - Anthracite (coarse)
 - sand (medium)
 - garnet (fine)
 - inert quartz stone. This distributes water during the backwash of the filtering media.



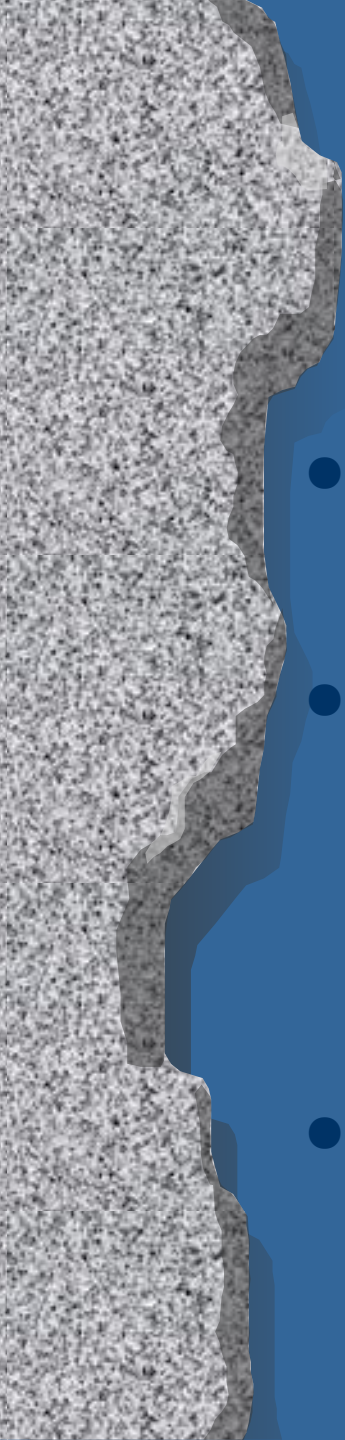
Particulate filters

- Operational flow is always down, while backwashing flow is always up.
- Can last many years
- Twin tanks coupled so both are on line, other than when one is in backwash.



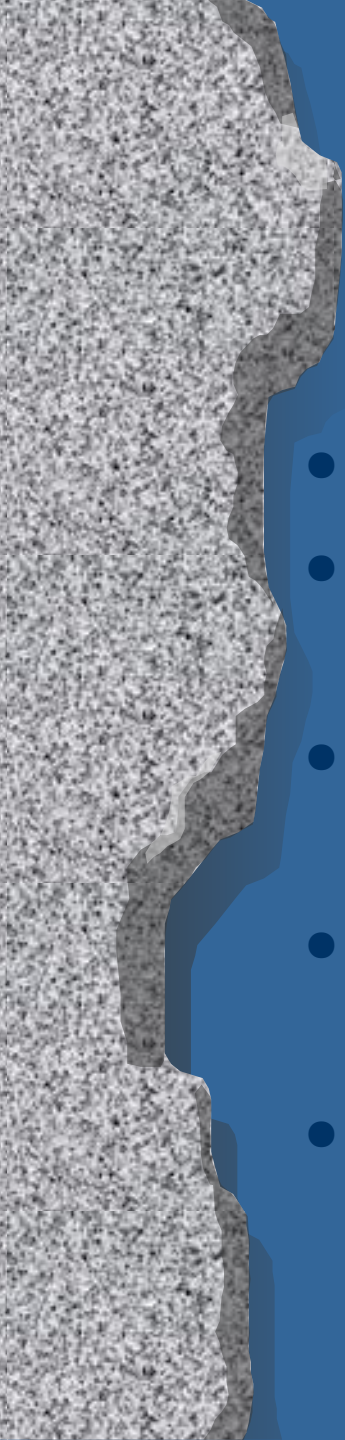
Particulate filters (cont'd)

- Other devices, such as activated carbon filters, slough particles. Filters need to be positioned downstream of such devices.
- Effectiveness measured by PRESSURE DROP across filter--once pressure drop rises above threshold, filters must be replaced.
- Measurement of municipal water turbidity, using “*plugging rate*”, is sometimes helpful--greater concern over small (<1 micrometer) particles



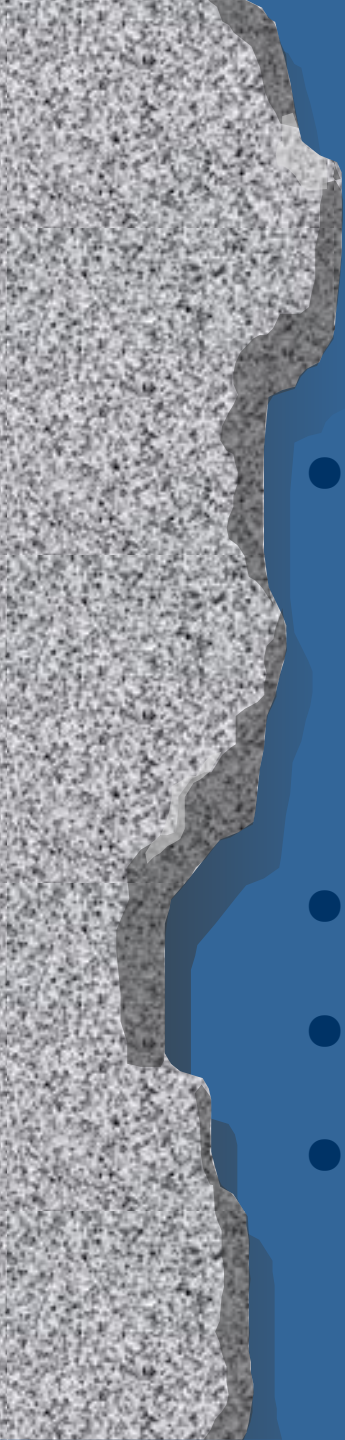
Particulate filters (cont'd)

- Are vulnerable to microbial contamination
- Although organisms can't cross dialysis membranes, pyrogens and endotoxin can--fever, chills and hypotension can result.
- Require regular disinfection



Softeners and deionizers

- Based on ion exchange
- Cationic resins: hydrogen ions (H^+) for cations
- Anionic resins: hydroxyl ions (OH^-) for anions
- Mixed bed: a mixture, so resulting H^+ and OH^- form water effluent
- Main benefit is all devices downstream **scale** less often and less severely



Softeners and deionizers (cont'd)

- When the exchange sites on a resin are depleted, the bed is said to be exhausted and needs regeneration for:
- Softener resins: brine
- Cationic resins: strong acids
- Anionic resins: strong alkali



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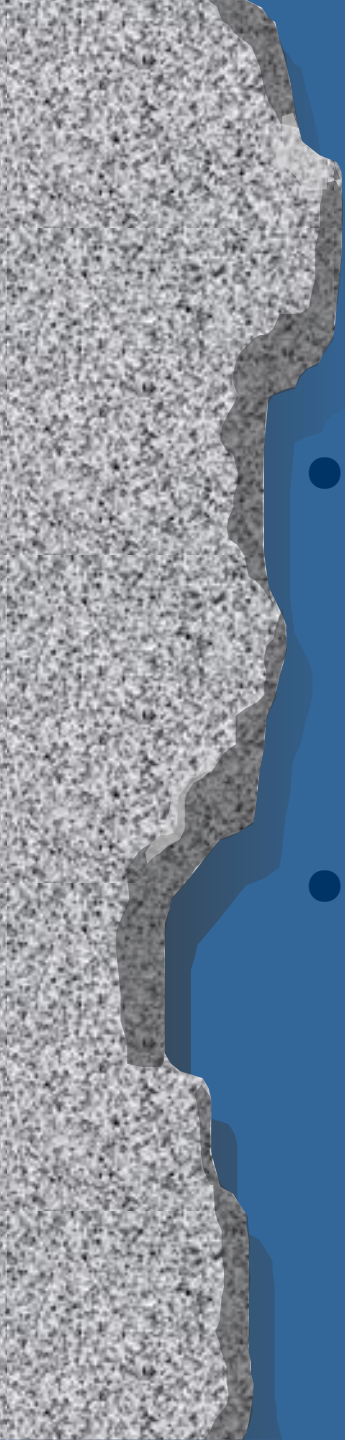
On-line Consulting

Ion Exchange Regeneration

Resin Type	Regenerate With	Other Conditions
Cation	5 lbs Hydrochloric Acid per cubic foot of resin	Rinse to pH 6.5 with high purity water
Anion	15 lbs Sodium Hydroxide per cubic foot of resin	100 degrees Fahrenheit. Rinse to pH 7.5
Softener	6 lbs Sodium Chloride per cubic foot of resin	Rinse free of brine solution

Volumetric Flow Rates - Schedule 80 PVC Pipe

PVC Schedule 80 Nominal Size	@ 1.5 ft/sec	@ 3.0 ft/sec	@ 5.0 ft/sec
1/4 inch	0.33 gpm	0.67 gpm	1.12 gpm
3/8 inch	0.66 gpm	1.31 gpm	2.19
1/2 inch	1.09 gpm	2.19 gpm	3.65 gpm
3/4 inch	2.02 gpm	4.04 gpm	6.74 gpm



Softeners and deionizers (cont'd)

- With on-site regeneration
 - safety features: bypass valves to prevent patient exposure to the brine, acids and alkali
- For commercial regeneration
 - must not be cross-contaminated by resins of non-medical users or microbial contaminants

Softeners and deionizers (cont'd)

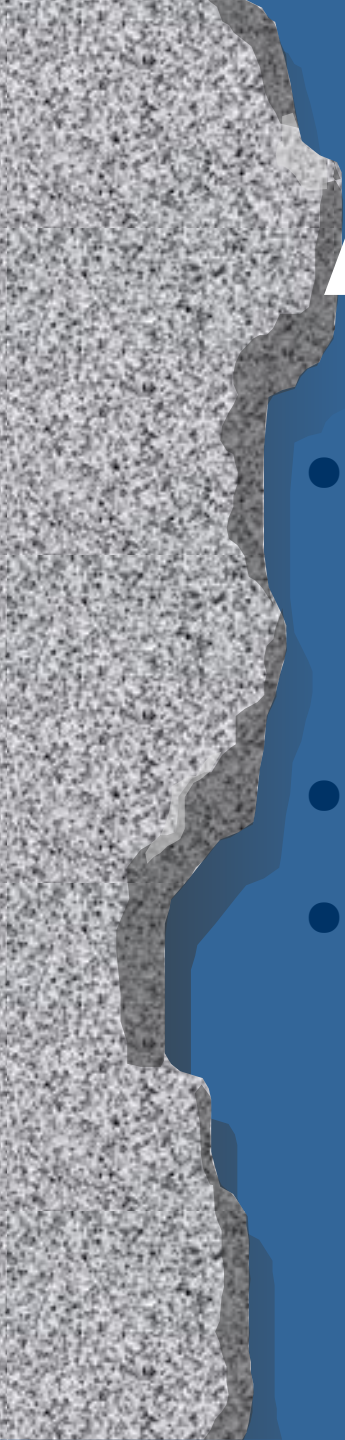
- Effectiveness of deionizers
 - **RESISTIVITY** of effluent water
 - Varies with temperature, which must be compensated
 - Mixed bed deionizers: resistivity > 1 megohm/cm
 - If below this, regeneration required
 - If not done, ions will leak off

Softeners and deionizers (cont'd)

- Affinities:
- Cationic: $\text{Ca}^{2+} > \text{Mg}^{2+} > \text{K}^{+} > \text{Na}^{+} > \text{H}^{+}$
- Anionic: $\text{NO}_3^{-} > \text{SO}_4^{-} > \text{NO}_2^{-} > \text{Cl}^{-} > \text{HCO}_3^{-} > \text{OH}^{-} > \text{F}^{-}$
- The low affinity for fluoride is particularly a risk, and can worsen osteomalacia and osteoporosis in patients (2)

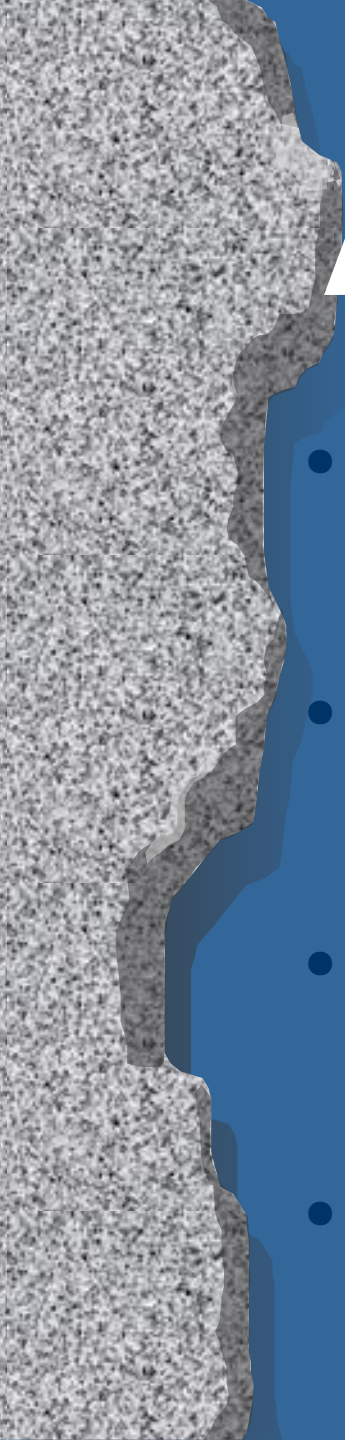
Softeners and deionizers (cont'd)

- Ion exchange capacity
 - in a mixed bed system, cationic > anionic.
 - Resulting effluent may be acidic.
 - Can leach copper from piping and dialysis machines--hemolysis and death can occur (3,4)



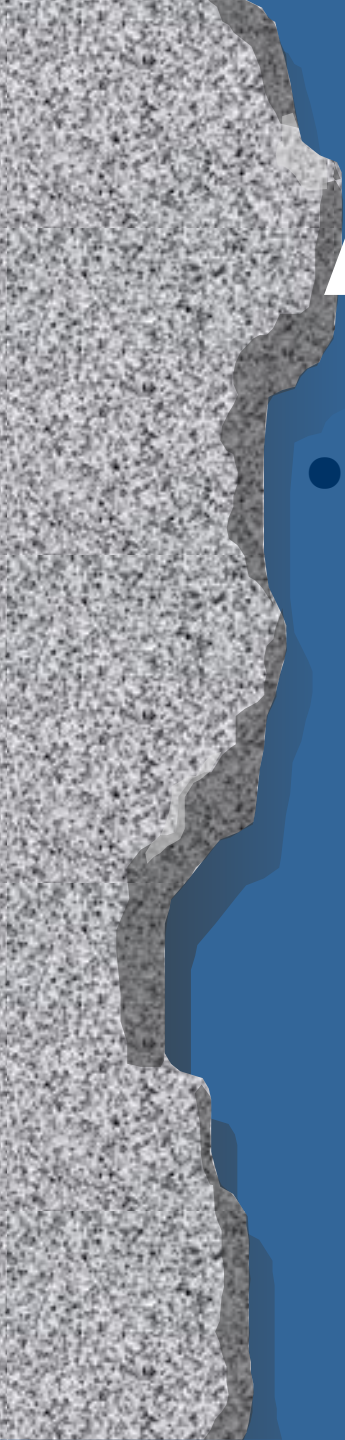
Activated carbon filters

- High adsorptive capacity for small organic contaminants (<300 daltons), chlorine and chloramines.
- Carbon usu activated by steam
- Replace when breakthrough of markers such as chlorine and chloramine detected in effluent.



Activated carbon filters

- Some reverse osmosis machines can be damaged by chlorine--activated carbon filters may be needed for pretreatment.
- Particulate filters are needed downstream of activated carbon filters (secondary clarification).
- Vulnerable to microbial contamination because of their structure and removal of incoming chlorine/chloramines.
- Regular disinfection downstream

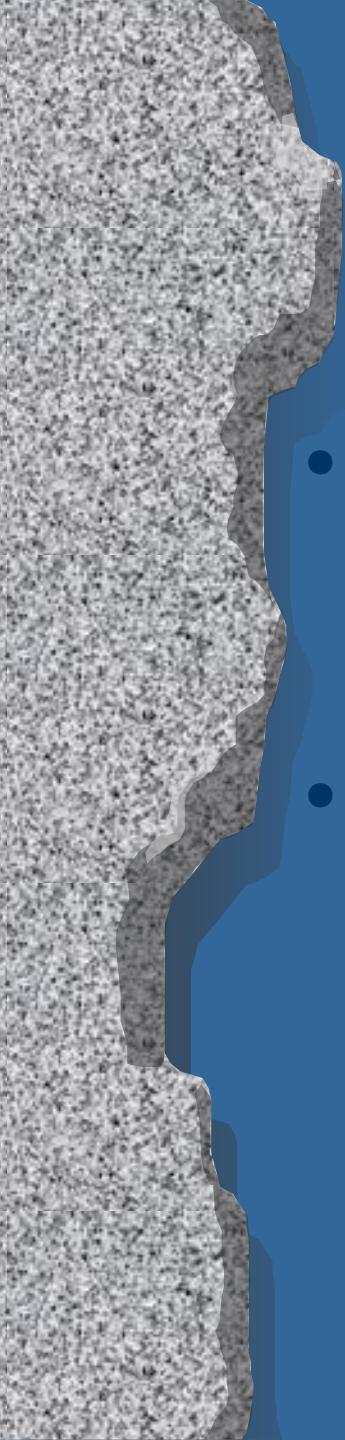


Activated carbon filters

- Chloramines are replacing chlorine in many areas, and can cause side effects (hemolysis, anemia, methemoglobinemia) (5) even at very low levels (0.25 mg/L)

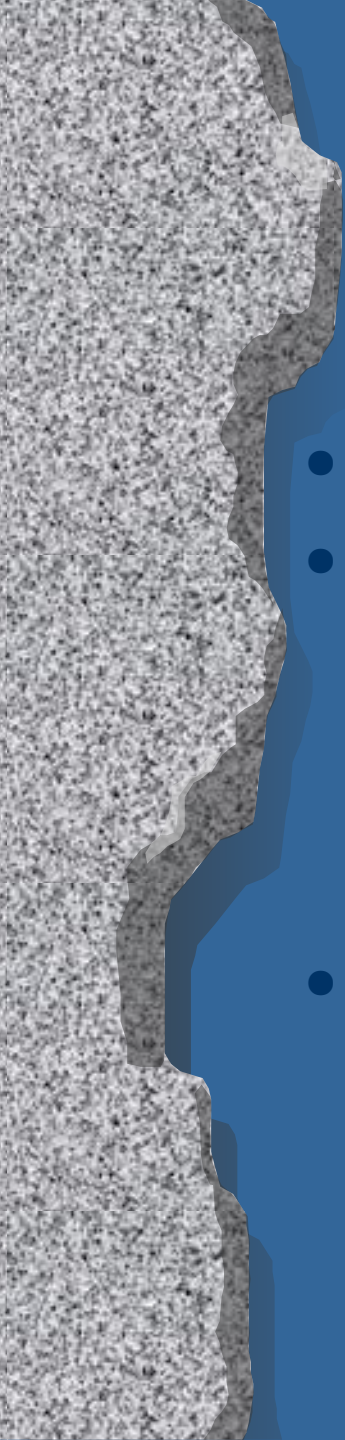
Reverse Osmosis

- Reverses flow of solvent due to osmosis
- Solvent flows across a semipermeable membrane from less concentrated to the more concentrated side.
- By applying a pressure that exceeds osmotic pressure, solvent flow is reversed
- Pumps are used in conjunction with a membrane module in flat sheet or hollow fiber configuration, usu with spiral design



Reverse Osmosis

- RO overcomes osmotic pressure and forces water through membrane pores about 5 micrometers in size with pressure usually supplied by a centrifugal pump (see below).
- Basic components:
 - Prefilter
 - pump
 - separators (spiral wound membrane elements), placed in stainless steel or PVC housing



Reverse Osmosis

- Operate in crossflow mode
- A single stream feeds into RO and flows across membrane surface, two streams exit:
 - Permeate (the purified water)
 - Concentrate (water that doesn't pass through membrane--goes to drain)
- This minimizes plugging of the membrane pores. Only a small percentage of feed water results in permeate.

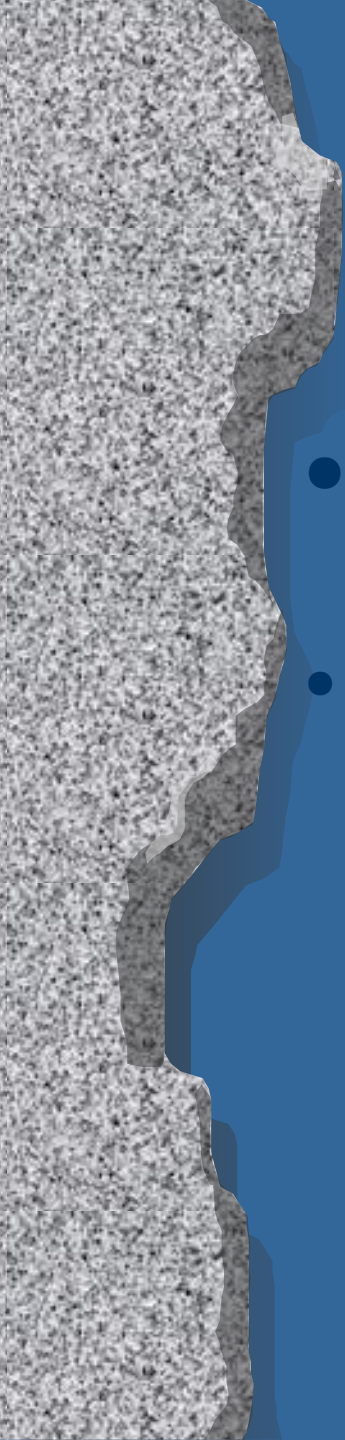
Reverse Osmosis

- The ratio between permeate to feed is called RECOVERY (product (or permeate) flow/(drain flow +product flow).
- The higher the recovery, the poorer the quality of the permeate.
- Large systems typically operate between 33% to 50% recovery.

Reverse Osmosis

- Other calculations often used:
- *Recirculation*: a means to enhance system efficiency through reduction in water consumption
- pump flow - (drain flow + product flow)

pump flow



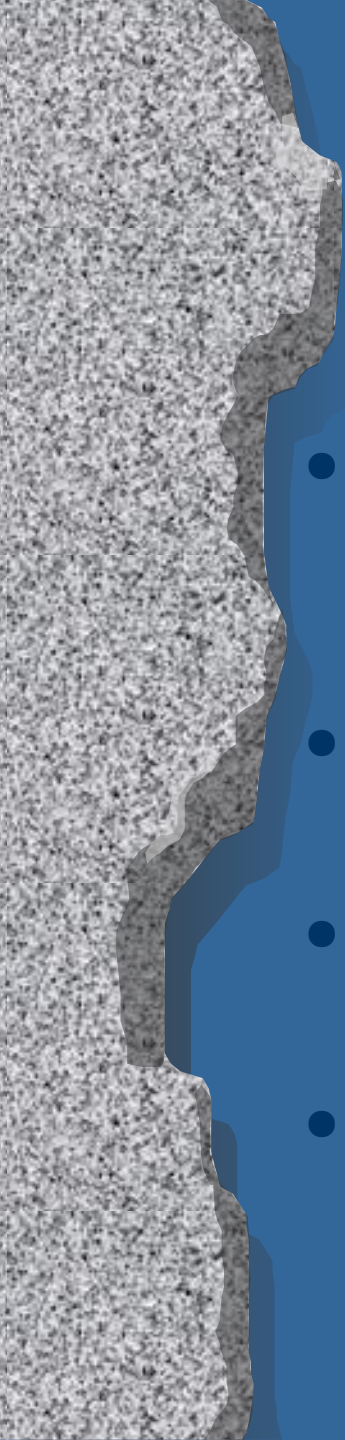
Reverse Osmosis

- *Rejection*: ability of the RO machine to purify water:
- feed water conductivity-product water conductivity

feed water conductivity

Reverse Osmosis (cont'd)

- Membranes reject 90-98% of monovalent ions (ie, sodium) and 95-99% of divalent ions.
- Also remove larger organic items (>200 daltons)
- Therefore useful for removing dissolved inorganic and organic contaminants, bacteria, pyrogens, and particulates.



Reverse Osmosis (cont'd)

- Cellulosic and synthetic membranes (similar to dialysis membranes) have been used.
- Performance is measured by **CONDUCTIVITY** of the feed water
- When below acceptable levels, membrane must be cleaned.
- Life of membranes can be prolonged several years by pretreatment

Reverse Osmosis (cont'd)

- Calcium, magnesium, and iron can form scales on RO membranes.
- Cellulosic membranes can be damaged by $\text{pH} > 8$ and bacteria.
- Some synthetic membranes can be damaged by chlorine and chloramines
- Startup costs can be high, but operating costs are modest. With high fluoride levels, polishing the product water with deionizers may be needed.

RO vs. DI

- Some centers use deionization (DI) instead of RO.
 - Removes ions from water via electrochemical attraction to a charged resin, encased in a fiberglass or steel tank. When saturated, must be taken offline and recharged, similar to softeners.

RO vs. DI

RO

Removes bacteria and pyrogen

Higher capital costs

Lower operating costs

DI

Does not, can actually increase these levels. Therefore, a membrane filter or UF machine is used downstream

Lower capital costs

Higher operating costs

RO vs. or with DI

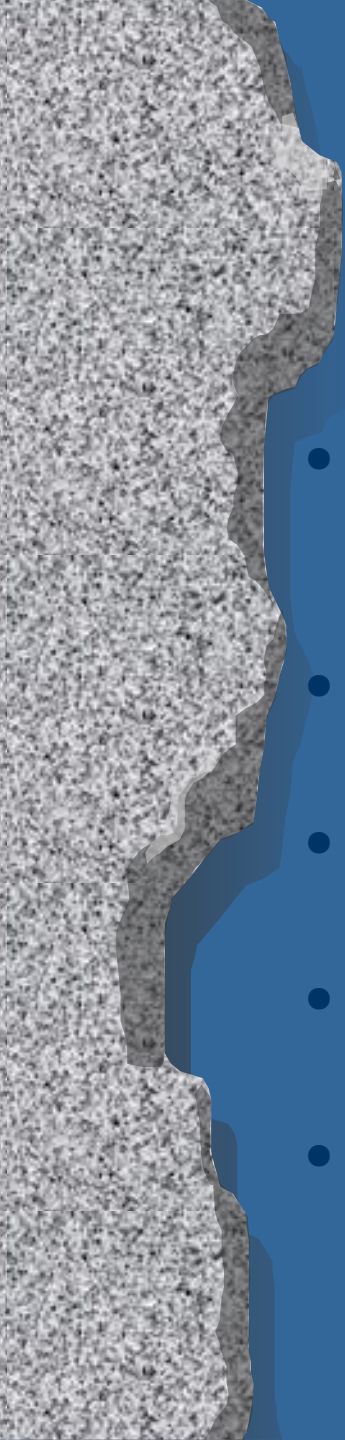
- If feedwater has a high dissolved solids level, a second RO in series or a DI unit operating on the RO permeate is needed.
- The operating costs of DI fed with RO permeate is much less than using untreated water.

AAMI categories

- Group A: Arsenic, barium, cadmium, chromium, copper, lead, nitrate, potassium, selenium, silver, sodium, sulfate, zinc
- Group B: Mercury
- Group C: Aluminum
- Group D: Calcium, magnesium
- Group E: Free chlorine and chloramines

RO vs. or with DI

- **Comprehensive analysis of substances listed in the prior AAMI tables should be obtained at the facility site (distributed water may differ from plant water). Each individual value is divided by its respective limit value available in the Standard, and summed. Three categories:**
 - **0-1: No treatment other than microbial and endotoxin measures**
 - **1-10: Additional purification by using either RO or DI for groups A-C, a softener or RO for group D, and GAC for group E.**
 - **10-100: Group A-C require double pass RO or single pass RO followed by DI, group D require either a softener plus RO or DI alone, group E require GAC**

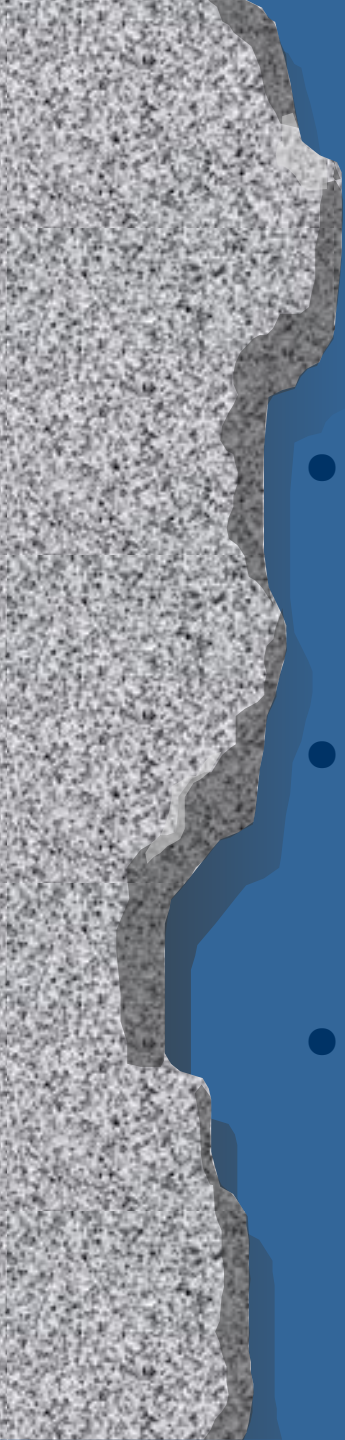


Ultrafiltration

- **Mainly used for DI systems. A membrane process similar to reverse osmosis but with a much more permeable membrane.**
- **Cannot reject ionic species but can reject viruses, bacteria, pyrogens, and particulates.**
- **Monitor PRESSURE DROP as for particulate filters**
- **Restored by backflusing and cleaning with chemicals.**
- **Useful as the last stage to control microbial and endotoxins**

Ultraviolet light

- Used selectively. UV light capacity must be related to volume flow rate of water. Radiant dosage should meet or exceed 30,000 $\text{mW}\cdot\text{s}/\text{cm}^2$ (surface area) of the flowing water stream. Wavelength should be 254 nm.
- Must include an intensity monitor

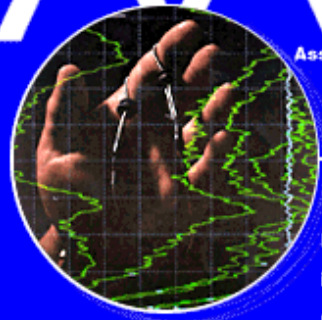


Pipe-Loop Distribution

- Should minimally incorporate continuous “drops” to each dialysis station
- No major “deadlegs” (side branches to dialyzer reuse machines or bicarbonate tanks)
- Necessary, but short, cleanable deadlegs where each dialysis machine attaches to its drop.

Water Quality Standards

- **AAMI (Association for the Advancement of Medical Instrumentation) sets standards based on FDA sponsored studies.**
- **Developed a comprehensive standard for hemodialysis systems including water quality.**
- **Standards address inorganic and bacterial contaminants, but NOT organic and radioactive contaminants other than those for drinking water standards.**



**Founded in 1967, AAMI
is a unique alliance of
users and manufacturers
of medical instrumentation
and technology united in
their dedication to the safe
use of medical technology.**

InSites: Links to the Net

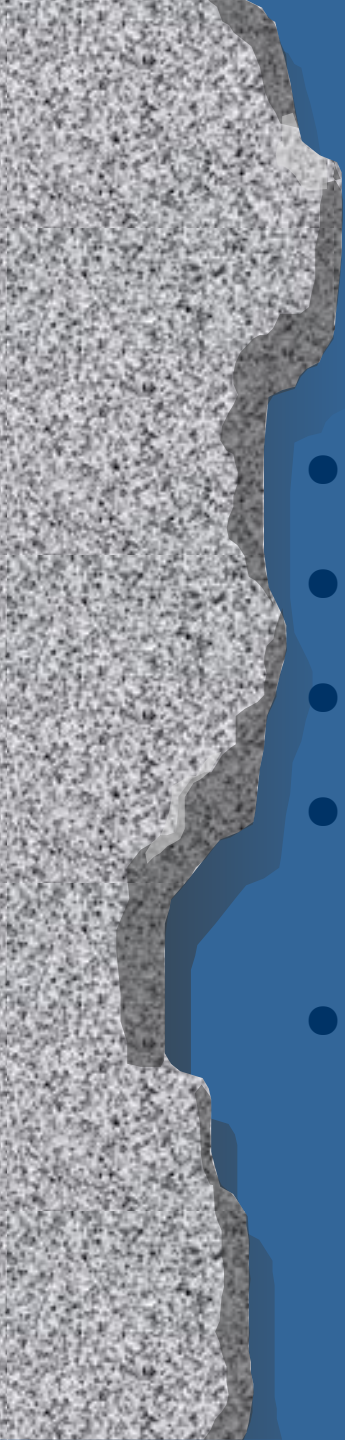
[\[Listserv\]](#) [\[Membership.Awards\]](#) [\[Meetings\]](#) [\[Publications\]](#) [\[Standards\]](#)

Water Quality Standards (cont'd)

- See tables for inorganic substances
- Bacterial contamination limit is 200 CFU/ml for water
- Limit for effluent dialysate is 2000 CFU/ml (based on CDC studies, (6,7)).
- No standards for endotoxin exist formally, but 1 ng/ml, limulus amebocyte lysate assay, has been established for water used for dialyzers reuse (AAMI)

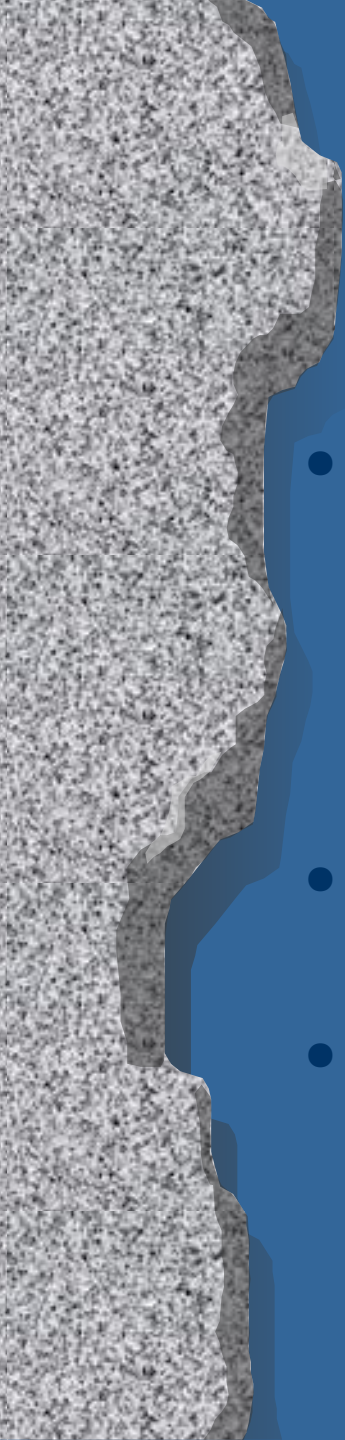
Water Quality Standards (cont'd)

- Counts can be factitiously elevated
 - Poorly designed sampling ports
 - Clues: both a rapid (apparent) resurgence in bacterial counts after a sanitation procedure and a profound decline in counts with multiple cultures from free flowing water from the same port over a short time (eg, repeated culturing q 5 min. *3).
 - The decline is because of “washout” from the sample port device. Sample ports without complex valve mechanisms and minimal deadspace should be used.
 - The sampling tube to culture specimens should be left in disinfectant solution between procedures, and rinsed free each time for cultures.



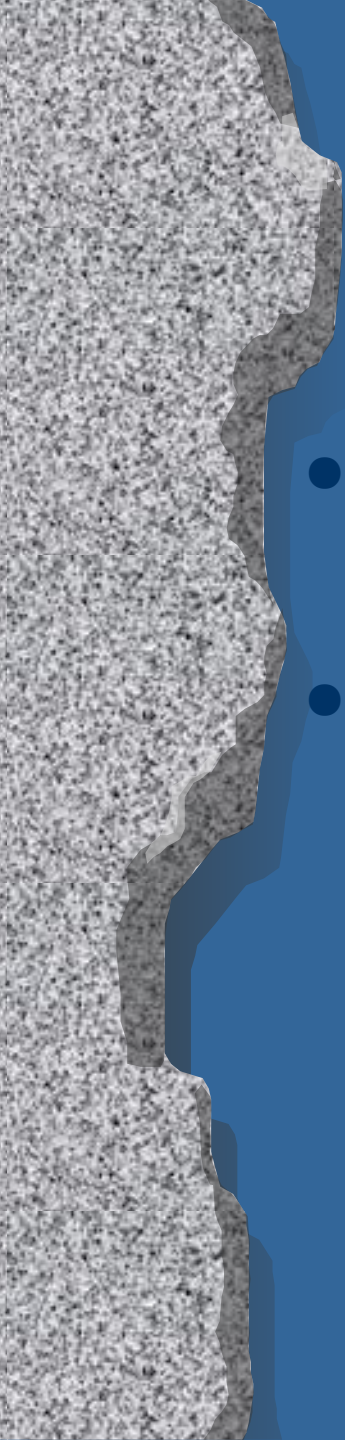
Water Quality Monitoring

- Resistivity--softeners and deionizers
- Conductivity--reverse osmosis
- Pressure drop--particulate filters
- Chlorine/chloramine effluent--activated carbon
- Also periodically monitor quality of the final product water of the entire system



Water Quality Monitoring

- AAMI recommends monitoring annually for chemical contaminants if reverse osmosis or deionization used, and q 3 months and at times of expected contaminant peaks in water supply for other devices.
- Monthly testing for bacterial contamination and additional testing as appropriate.
- More frequent monitoring when a system is first installed, transition to less frequent monitoring when safe levels shown.



Sanitizing the system

- Maintain proper levels of agent for proper time
- When complete, confirm the absence of the agent from processed water stream and effluent dialysis water.

Choice of sanitizing agents

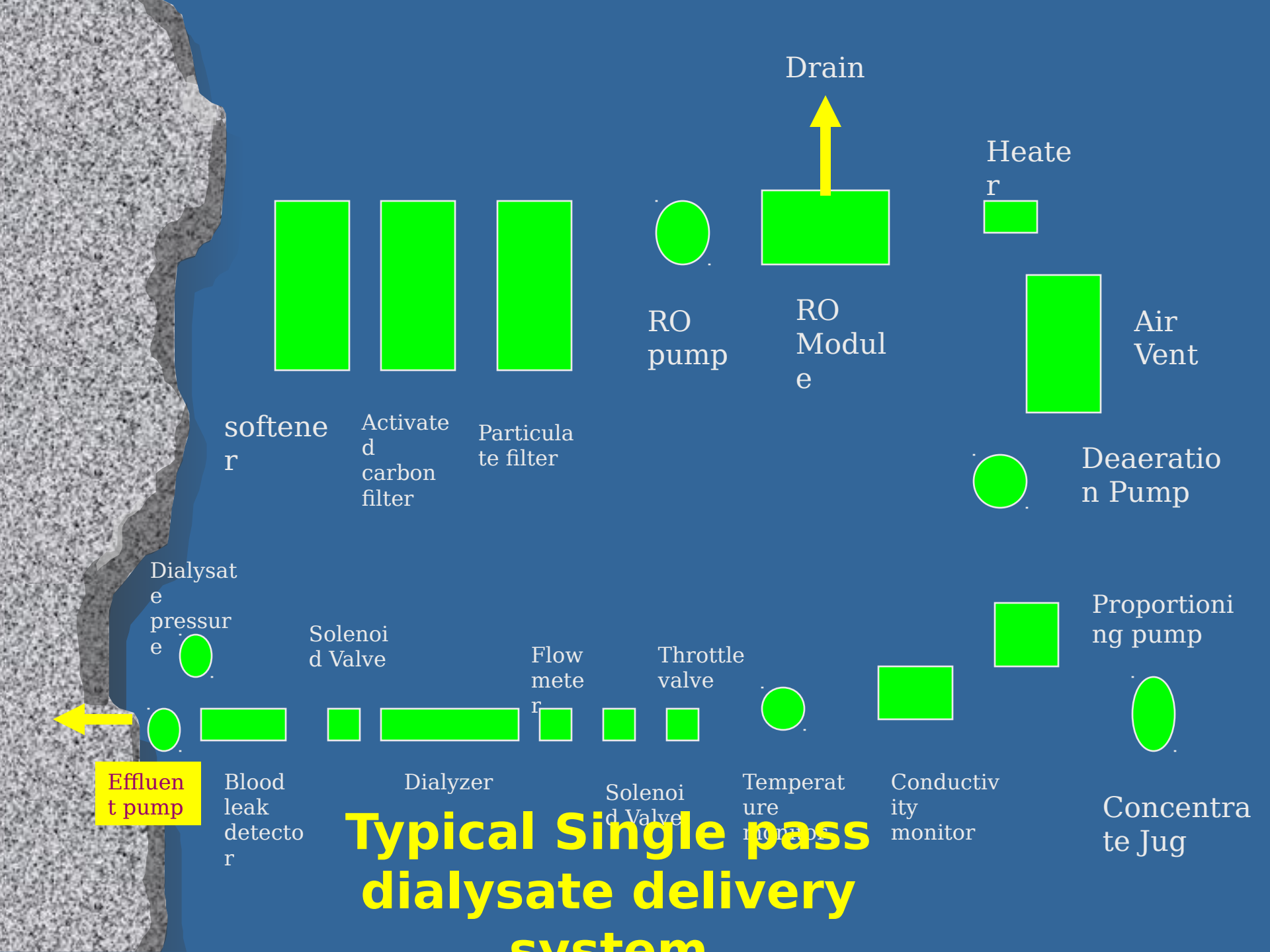
- Bleach (sodium hypochlorite) --corrosive and less effective than formaldehyde or peracetic acid, but very effective against biofilm.
- Purogen (chlorine dioxide)
- Minncare (acetic acid, peroxyacetic acid, and peroxide)
- Renalin (peracetic and hydrogen peroxide, mainly used in dialyzer reuse--recent controversy)
- Formaldehyde
- Heat (85-90 deg C)

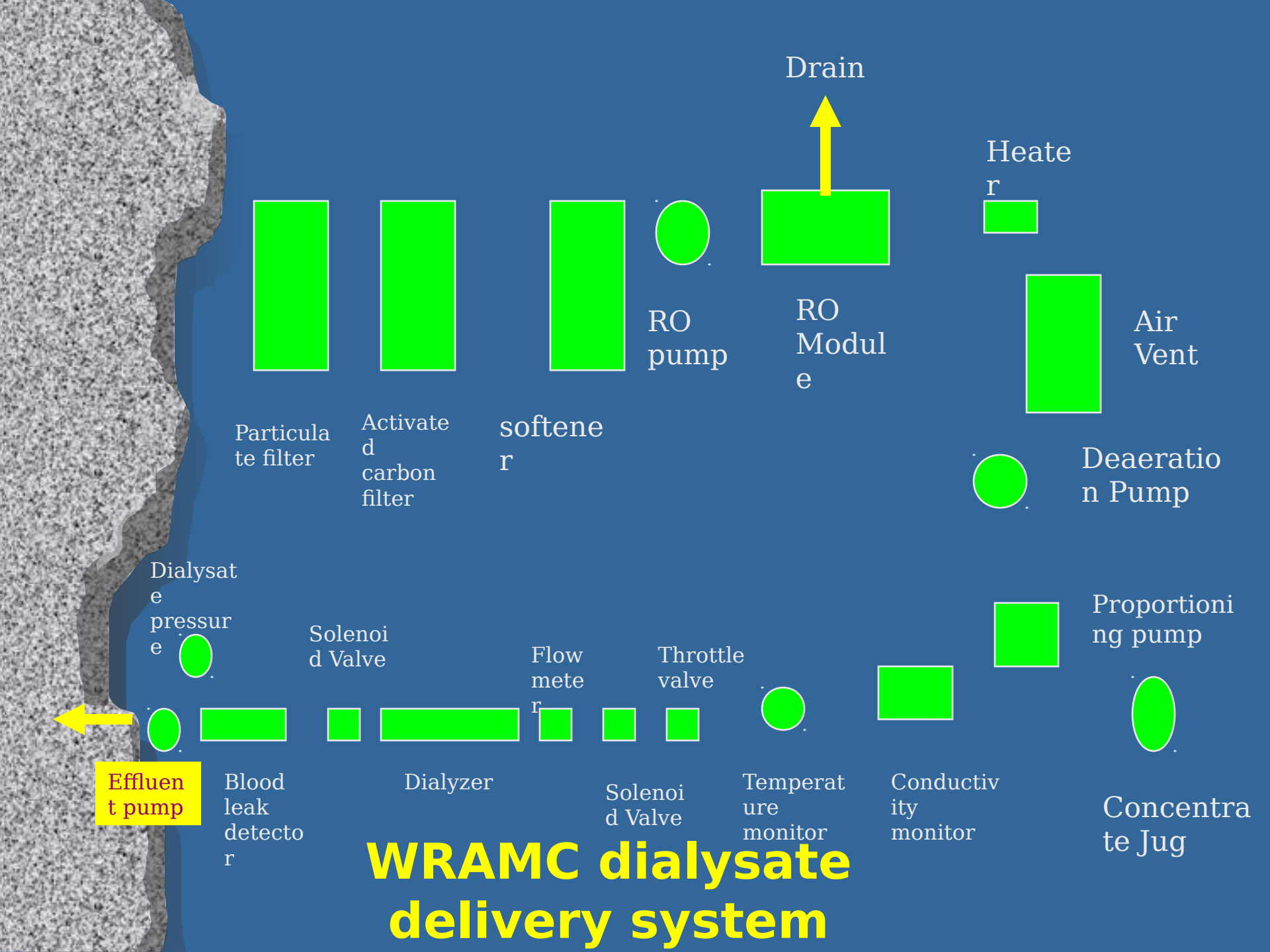
Sanitizing

- Ensure inlet flow path is exposed (may employ recirculation to do this)
- Prevent the operator from switching the delivery system on during a disinfection cycle. Should be incorporated into the system.

Formaldehyde

- **Not allowed in the NCA, but often used as the “last resort”**
- **If patients exposed, can cause burning, smothering sensation, and hypotension**
- **Chronic exposure may include neurologic disturbances, metabolic acidosis, and hemolysis**
- **the Clinitest cannot detect levels below 15 microgm/mL and should not be used with glucose containing dialysate.**
- **Formaldehyde not effective against *Mycobacterium chelonae*--need concentrations of 4% and longer periods**







Critical Care Services, Inc.

Technical Assistance

The consulting services are open 24 hours a day to provide technical assistance.

Water Treatment System Troubleshooting Guide

- [There is insufficient pressure and /or flow to operate the system](#)
- [There is chlorine in my GAC product water](#)
- [I have hardwater after the softener](#)
- [The total dissolved solids in my RO water are high](#)
- [I just put new DI tanks in service and my resistivity meter still indicates less than 10 megohm](#)
- [I have persistent bacteria and/or endotoxin in my product water](#)
- [My water analysis shows high aluminum levels in my product water](#)
- [I have high fluoride levels in my product water](#)
- [I've tried all of the above, and I'm still having problems](#)

[Conversion Tables](#)[Water Treatment Calculation Formulae](#)[Water Quality Standards](#)







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REAGENT
STRIPS**
Test for
total
hardness
in water
50

**HARDNESS
REAGENT
STRIPS**
Test for
total
hardness
in water
50
Test Strips

**CHLORINE
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STRIPS**
Test for
levels of
residual
chlorine in
free water
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